

REMARKS

I. Status Summary

Currently, claims 1-6 are pending. Claims 1-6 presently stand rejection. Within this Amendment, claims 1-6 have been amended. Applicant respectfully submits that the Amendments to claims 1-6 do not raise issues of new matter and does not require further consideration or search by the Examiner. Further, Applicant respectfully submits that the Amendment and the remarks below place claims 1-6 in condition for allowance or in better condition for appeal, as discussed in greater detail below. Reconsideration of the application and entry of the Amendment is respectfully requested.

II. Claim Rejections under 35 U.S.C. § 102(b)

Claims 1-6 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,467,793 to Ender (hereinafter, "Ender"). Further, claims 1 and 3-5 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,483,335 to Tornier (hereinafter, "Tornier").

Applicants note that it is well settled that for a cited reference to qualify as prior art under 35 U.S.C. §102, each element of the claimed subject matter must be disclosed within the reference. See Hybritec, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 231 U.S.P.Q. 81 (Fed. Cir. 1986) (stating that "[i]t is axiomatic that for prior art to anticipate under 102 it has to meet every element of the claimed invention"). Accordingly, Applicant respectfully submits that neither Ender nor Tornier disclose every element of claims 1-6 and therefore cannot anticipate these claims under 35 U.S.C. §102(b).

II. A. Summary of the Independent Claims 1, 5, and 6

Rejected under 35 U.S.C. § 102(b)

Claim 1 recites a longitudinally extending intrafocal plate for securing bone fractures. The intrafocal plate includes elongated intrafocal plate element having a surface at one end thereof defining a top, bottom, a leading end, and a trailing end and sized to overlay a fracture site. The elongated intrafocal plate has a longitudinally length extending intrafocal resilient body element integral at one end thereof adjacent to but spaced apart from the trailing end of the surface so as to define an overhanging heel between the location at which the resilient body element is integral to the surface and the trailing end of the surface wherein the heel serves to help stabilize the fracture site. The body element is formed to extend generally in the lengthwise direction of the surface and wherein the other end of the body element defines a pin element.

Claim 5 recites an intrafocal plate for securing bone fractures. The intrafocal plate includes an elongated intrafocal plate element having a surface at one end thereof defining a top, bottom, leading end and trailing end and sized to overlay a fracture site. The intrafocal plate has a longitudinally extending intrafocal resilient body element integral to the surface at one end thereof adjacent to but spaced apart from the trailing end of the surface so as to define an overhanging heel between the location at which the resilient body element is integral to the surface and the trailing end of the surface wherein the heel serves to help stabilize the fracture site. The other end of the body element defines a pin with the intrafocal plate including one or more screws for insertion through one or more apertures define in surface of the plate element.

Claim 6 recites a longitudinally extending intrafocal plate for securing metaphyseal bone fractures. The intrafocal plate includes a elongated intrafocal plate

element having a surface at one end thereof with one or more apertures therein in defining a top, bottom, leading end and trailing end and sized to overlay a fracture site. The intrafocal plate has a longitudinally extending intrafocal resilient body element integral to and depending from the trailing end of the surface so that the body element forms an acute angle with the surface and extends generally in a lengthwise direction of the surface. The body element is adjacent to but spaced apart from the trailing end of the surface so as to define an overhanging heel between the location at which the resilient body element is integral to the surface and the trailing end of the surface wherein the heel serves to help stabilize the fracture site. The body element defines a shoulder at one end at the juncture of body element and the surface with a pin at the other end of the body element.

II. B. Arguments Against the Rejections of the Claims based 35 U.S.C. § 102(b)

Applicant respectfully submits that Ender does not anticipate independent claims 1, 5, or 6 or the claims that depend therefrom. In particular, Ender does not disclose all the features of claims 1, 5, and 6.

Ender discloses a resilient bone nails 4 consisting of elastic material and being bent at proximal end portions that are insertable into a medullary canal 3 of a bone 1. The bone nails 4 are provided at the respective distal end with a coupling member (not shown) allowing a wholly non-rotatable connection with an impact tool. This coupling member is formed of a small plate-like flattening of the distal nail end and is provided with a slot for enabling removal of the inserted nail. Ender further discloses an insert member 5 that is a separate modular component from the resilient bone nails 4. The insert member 5 has a guide channel 6 which is arranged such that the nails 4, when

forcibly introduced, run into the medullary canal 3 in the desired manner. The insert member 5 is provided with a flange contacting the outer surface of the bone 1 and preventing the insert member 5 from entering the medullary canal for too great a distance. The nails 4 are introduced to such a depth that their distal ends, provided with the coupling member, are accommodated within the guide channel 6, i.e., are not outwardly protruding and irritating overlying sinews and muscles, but also do not slide in the medullary canal.

The insert member 5 is a specifically separate component from the resilient bone nails 4 to allow the insert member 5 to be inserted into and positioned around and within the impact hole before the bone nails 4 are to be inserted. Thus, the resulting functionality of the device of Ender can only be achieved in a two-piece, modular design.

The device of Ender is used in four steps. First, an impact hole is created. Second, the insert member is placed in the impact hole. Third, the resilient bone nails are inserted into the medullary canal through the insert member and impact hole with a modular impact tool. Fourth and finally, the nail is coupled to the insert member. Thus, Ender discloses an insert member which is a separate and distinct component from the resilient bone nails used therein.

As stated above, the coupling member and insert member of Ender permit the nail to be driven into the bone to such a depth that it's distal end is accommodated by (in) the insert member and thus does not protrude so that irritation of the muscles is prevented which occurs on other nails with external coupling members. The resulting functionality of the device of Ender to prevent the coupling member from irritating the

muscles that still allow it to be able to lock to the bone distally can only be achieved in a two-piece, modular design as described by Ender.

The insert member and the coupling member of Ender have another function which is to prevent the coupling member from entering the interior of the medullary canal and thus disappearing within the bone, resulting in a reduction of the tensile stress needed to hold the fracture fragment in place. The coupling member and insert member function secondarily, if the above condition were to occur, to prevent the nail tip from penetrating the condyles of the bone (this would actually be the femoral head) and ultimately penetrating the socket or opposite side of the joint. The insert member must be a separate piece from the nail in Ender to perform its function of preventing the coupling member of the nails from entering the interior of the medullary canal and to prevent the tips of the nails from penetrating the condyles of the bone and ultimately penetrating the socket or opposite side of the joint.

Claims 1, 5, and 6 of the present application recite that the intrafocal plate element of the intrafocal plate is integral to the body element. Therefore, the intrafocal plate element and the body element of the intrafocal plate are a single unitary device. Thus, by contrast, the intrafocal plates of claims 1, 5 and 6 can be used in two steps: 1) inserting the device into the fracture site and 2) seating the heel on the bone cortex while reducing the fracture fragment. Since Ender does not disclose such a single unitary device, it does not anticipate independent claims 1, 5, and 6.

Further, the device of Ender is used to fix per and subtrochanterous fractures. A further function of the insert member is to prevent the impact hole from becoming splayed during the driving or insertion of the nails and thus preventing the impact hole

from becoming enlarged and the bone from collapsing at the contact area. The nail is rotated once the correct penetration depth is achieved to reduce the fracture to the correct position. The insert member is designed with a flange 7 that protects the bone in the vicinity of the impact hole. To assure circumferential protection of the bone surrounding the impact hole a circumferential flange is shown in the drawings. "The forces exerted by the coupling members of the nails subjected to tension stress are rather supported by the insert member and transmitted by this insert member on the bone in an equal manner over the whole circumference of the impact hole so that even with older humans having porous bones any danger of a break down of the bone at the area of the impact hole is avoided." (See Ender, col. 2, line 63- col. 3, line 2.) The function of the heel on the present application is to prevent overreduction of the fracture fragment to the opposite side of the bone. Because the overhanging heel of the present application is not used to protect the bone surrounding the impact or entry hole, its structure does not need to be circumferential. The heel structure in fact is just a longitudinal extension of the trailing edge of the plate element.

The Examiner's argument that "the device [of Ender] is capable of being inverted and attached at the fracture site if the surgeon chooses to do so," is not based on the universally known biomechanics of flexible IM nails or the function and structure of the device of Ender, in particular. The proximal tip of the device of Ender needs to extend into the fracture fragment. The tip of the device of Ender must pass beyond the fracture site. If the device of Ender were attempted to be placed inverted as suggested by the Examiner, an entry hole would have to be placed through the articular surface of the bone thereby destroying healthy articular cartilage. It would require the insert member

to be placed on the articular surface of the humeral head which would result in painful articulation of the head in the socket and eventual destruction of the socket. The Examiner could argue that the device could be placed in the notched area just above the fracture **2** in Figure 2 of Ender. This would result in little to no purchase of the nail in the fracture fragment and since the insert member is external to the bone it would result in loss of motion due to impingement on the socket during articulation. The biomechanics of flexible IM type nails like those of Ender require a three-point fixation to stabilize the fracture fragment. One point of the fixation is an intact impact hole. If the impact hole is the fracture site, as suggested by the Examiner, stability of the fracture fragment will not occur as you are trying to stabilize the fragment to a structure that itself is unstable. This is the exact reason for the insert member: to protect the bone surrounding the insert member. Poor or destroyed bone will prevent one of the three fixation points.

For the above reasons, Applicants respectfully submit that Ender does not disclose all the structural features recited in claims 1, 5, and 6 or the claims that depend therefrom.

Applicant respectfully submits Tornier does not anticipate independent claims 1 and 5 or the claims that depend therefrom. In particular, Tornier does not disclose all the features of claims 1 and 5.

Tornier discloses a nail **8** that is bent twice at one end in opposing directions so as to form a shoulder **8a** substantially perpendicular to the preceding portion of the nail and to form a flattened plate portion **8b** that extends outward from the shoulder **8a**. Tornier does not disclose an overhanging heel that extends backward in the opposite

direction of the plate 8b from the shoulder 8a. The plate portion 8b only extends on one side of the shoulder 8a. The plate 8b does not extend on both sides of the shoulder 8a. Thus, Tornier does not disclose an overhanging heel as recited in claims 1 and 5.

Claims 1 and 5 specifically recite an overhanging heel between the location in which the resilient body element is integral to the surface of the intrafocal plate element and the trailing end of that surface. The overhanging heel overhangs the body element. Tornier only discloses a plate portion 8b which extends outward from the nail 8 and does not have any portion that overhangs the nail 8. Thus, Tornier cannot perform the function of preventing overreduction of the fracture fragment on the opposite side of the bone.

For the above reasons, Applicants respectfully submit that Tornier does not disclose all the structural features recited by claims 1 and 5 or the claims that depend therefrom.

For the above reasons, Applicants respectfully submit neither Ender nor Tornier anticipate independent claims 1, 5 or 6. Since claims 2-4 depend from claim 1, Applicants respectfully submit neither Ender nor Tornier anticipate claims 2-4 as well. Applicants, therefore, respectfully request that the rejections of claims 1-6 under 35 U.S.C. § 102(b) be withdrawn and the claims allowed at this time.

CONCLUSION

In light of the above amendments and remarks, it is respectfully submitted that claims 1-6 of the present application are now in proper condition for allowance, and an early notice to such effect is earnestly solicited.

If any small matter should remain outstanding after the Patent Examiner has had an opportunity to review the above Remarks, the Patent Examiner is respectfully requested to telephone the undersigned patent attorney in order to resolve these matters and avoid the issuance of another Official Action.

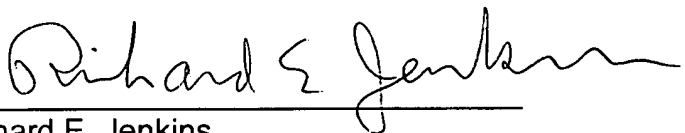
DEPOSIT ACCOUNT

The Commissioner is hereby authorized to charge any fees associated with the filing of this correspondence to Deposit Account No. 50-0426.

Respectfully submitted,
JENKINS, WILSON, TAYLOR, & HUNT, P.A.

Date: January 19, 2007

By:


Richard E. Jenkins
Registration No. 28,428

REJ/DMS/sla/gwc

Customer No: 25297